NSF Cook & Thurber
An NSF International Company

Food Safety, Quality and Food Defense Audit

Company Information		Audit Information	
Facility:	T3836 - ROSS PRODUCTS - ABBOTT LABORATORIES	Audit#-Visit#:	122948 - 99686
Address:	1250 W MARICOPA HWY CASA GRANDE, ARIZONA UNITED STATES , 85222	Audit Type:	BASE1-Food Safety, Quality and Food Defense Audit
Contact:	MS. SHARON BOTTOCK	Template Version:	1.4
Title:		Audit Categoty:	REGULAR
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Email:		Audit Start Time:	08-APR-2008 08:00:00 AM
		Audit End Time:	08-APR-2008 05:00:00 PM
		Prior Audit Date:	09-APR-07
		Prior Audit Score:	95.73%

Facility And Operating Profile

No	Question/Notes
1	Facility and Operations Description: Auditor's Notes: Ross Products is a division of Abbott Laboratories. The division has 5 manufacturing locations and is headquartered in Columbus, Ohio. The Casa Grande facility is about 700,000 square feet on a 240-acre lot on the west side of town. It was built in 1985. There are 4 production lines and all products are shelf stable and of a medical nutritional nature. 450 personnel are employed at this location and production operates 24 hours a day, 7 days a week with sanitation performed by in-house personnel as scheduled.
2	Regulatory Inspection Type: Regulatory Inspections include: FDA; State and Pinal County.
3	Products made at this facility: Powdered and liquid infant formulas.
5	What is the average lot size in pounds (coded and identifiable)? 210,000 lbs.
6	What is the most probable cause of accidental product contamination? See Note Extraneous product material (small black specs of scorched material--very infrequent) and from the Consumer, even though the container has a replacement lid to be utilized after the original seal is broken and the metal lid removed.
7	The following departments and individuals participated in the audit process: See Note Operations Manager, Victor Yubeta; Sharon Bottock, Quality Assurance Manager; Jeffrey Starling; Several supervisors on the production floor.
Section Notes:	

11-cv-4017MWBT

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Score Summary By Section		
Section Name		Section Score
Section A - Administration and Regulatory Compliance		97.00%
Section B - HACCP Management		97.00%
Section C - Facilities and Equipment		98.00%
Section D - Sanitation, Housekeeping and Hygiene		96.00%
Section E - Rodent and Pest Control Management		96.00%
Section F - Receiving and Inventory Control		97.00%
Section G - Process and Product Evaluation		97.00%
Section H - Packaging and Labeling		97.00%
Section I - Storage and Shipping		96.00%
Section J - Analytical Records and Laboratory Support		98.00%
Section K - Food Defense		97.00%
Food Safety, Quality and Food Defense Audit Average Score:		96.91%

Category Scoring Guide

95-100 = Meet or Exceeds Audit Expectations (Acceptable - Excellent)
85-94 = Opportunity For Improvement (Minor)
75-84 = Needs Improvement (Major)
<75 = Immediate Improvement Needed (Critical)

Automatic Audit Failure

Direct Product Contamination.
Adulterated or Misbranded product .
Facility was not operating in sanitary condition.
HACCP System Failure - Plant was producing product that did not meet critical limit(s); appropriate corrective action was not taken; or no HACCP Plan if mandated by regulations.
Critical Deficiency in any one category.

Overview

No	Question/Notes
	Notes from the auditor: See Notes Ross Products is a division of Abbott Laboratories, with multiple factory locations. They are a world wide shipper of flavored liquid and dry fortified nutrition products. The division has 5 manufacturing locations and is headquartered in Columbus, Ohio. The Casa Grande facility is about 700,000 square feet on a 240 acre lot on the west side of town. 450 personnel are employed at this location and production operates 24 hours a day, 7 days a week with sanitation performed by in-house personnel as scheduled. The facility was built about 23 years ago and has been maintained, both internally and externally, to original conditions. They have a management team that is involved very closely in the total day to day operations. Management maintains an employee base that is dedicated, committed and stable for the production of superior quality products. Equipment throughout the facility is state of the art, primarily computer operated and monitored for precise controls at all phases of the operation. Based on this system, documentation of all events are actively recorded and maintained for future reference. They receive a very detailed annual review of all operations, lasting 1-2 weeks, from their own corporate review group. A detailed FDA 3-day review was recently completed and the report contained a very factual, detailed description of the total operations for all products and identified that all criteria met regulatory compliance. Label security is highly maintained throughout the plant operations. After the labels are selected for a product run they are placed in a secure, locked cage with a bar code tag designated for each line of operation. This prevents the risk of erroneous labels being applied, since they manufacture both milk and soy protein based items. All materials are controlled with the item name, lot number and bar code identifiers.
Section Notes:	

Section A Administration and Regulatory Compliance

No	Question/Notes	Answer
1	Food Safety, Quality and Food Defense Organization and Responsibilities There must be a plant management organization chart that shows the reporting structure of the plant operating departments. The chart must clearly show the reporting relationship of the Quality Manager.	Acceptable
2	Food Safety, Quality and Food Defense Policies and Procedures There must be policies and procedures that address relevant food safety, quality and security requirements for the receiving, handling, manufacturing and shipping of product.The expectations should be defined through product and process specifications, testing procedures, sampling programs and accept/reject criteria.	Acceptable
3	Specific Training Goals and Programs for Management and Operating Personnel Documents must be available to demonstrate managements commitment to a planned training program for both management and food production personnel. The plan must include training of all new employees and refresher training for all current employees on a regular basis. Refresher training is provided on a regular basis, is documented on an individual basis and includes testing to document understanding. Supervisors and above must attend an academy training program at the divisional training location.	Excellent
4	Recall Plan and Procedures A plant specific Recall Plan must be available. The plan must include all necessary contact information. All documentation related to product traceability must be available. A traceability exercise must be conducted at least twice per year.	Acceptable
5	Regulatory Compliance The facility must maintain a file of regulatory actions, visits, reports or other notifications received from any regulatory agency. Written responses with appropriate corrective actions must be documented. A log of samples submitted for pathogen, antibiotic or environmental testing must be maintained.	Acceptable
6	Document and Records Management A document control policy must be in place that covers all aspects of creating, storing and disposing of documents. A document control policy is in place that identifies current revision status, specifies time limit for holding of files and indicates proper disposition of outdated documents and records.	Excellent
7	Change Management There must be a policy in place to manage and communicates changes in specifications, policies and procedures in order to maintain continuity and the control of systems.	Acceptable
8	Documentation to Track Effectiveness of Policies Management reviews must take place to evaluate the level of conformance to operational policies.	Acceptable
9	Management Awareness and Commitment to Food Safety, Quality & Food Defense Management must be committed to food safety and quality. There active support should be shown through training programs, auditing for compliance to policies and provision of corrective actions.	Acceptable
10	Crisis and Natural Disaster Management A crisis management plan must be in place that defines emergency procedures, outlines the crisis team members and provides key contacts with 24/7 access.	Acceptable
11	Customer/Consumer Complaints (Policies, Follow Up and Response) There must be a customer complaint program in place that addresses responsibilities, response time and corrective actions based on the investigation of a complaint.	Acceptable
Section notes:		

Section B HACCP Management

No	Question/Notes	Answer

Section B HACCP Management

No	Question/Notes	Answer
1	Prerequisite Programs Prerequisite programs must be well developed, documented and monitored. Complete flow charts for each prerequisite are developed with details identifying specific functions.	Excellent
2	Preliminary HACCP Tasks A HACCP team must be assembled with team member responsibilities clearly identified. Process flow diagrams outlining each step in the process must be constructed by the HACCP Team and they must perform an on site review to verify its accuracy.	Acceptable
3	Hazard Analysis (HACCP Principle 1) The HACCP team must prepare a list of all chemical, physical and biological hazards that may occur and conduct a hazard analysis to identify the hazards that are critical and controllable.	Acceptable
4	Critical Control Points (HACCP Principle 2) Documentation for determining a step or process as a CCP or not, must be clearly explained. Meetings must be conducted on a regular basis by the HACCP team to review any changes in the process that might affect the CCP determination.	Acceptable
5	Critical Limits (HACCP Principle 3) Control measures identifying operating and critical limits must be established and for each CCP. All critical limits must be measurable. Process capabilities must be documented to establish that CCP limits are compatible with the plant process and that limits are attainable.	Acceptable
6	CCP Monitoring (HACCP Principle 4) CCP monitoring procedures must be conducted at a frequency sufficient enough to detect any loss of control.The data must be evaluated by those empowered to implement corrective actions and must be documented on HACCP records.	Acceptable
7	Corrective Actions (HACCP Principle 5) Corrective actions must be developed for each CCP including instructions with the necessary actions to take to secure product and bring the CCP under control in the event a critical limit is exceeded.	Acceptable
8	Verification and Validation (HACCP Principle 6) Documentation must be available confirming the HACCP plan is scientifically and technically sound. The documentation should also confirm that all hazards have been identified and CCPs are effective and valid. Validation of the plan must be performed and documented on an annual basis.	Acceptable
9	Documentation and Record Keeping (HACCP Principle 7) HACCP procedures must be documented with detailed corrective actions and product dispositions. Final records must be in ink, signed by the appropriate personnel and without missing data or blanks. Records must be securely stored and easily retrievable.	Acceptable
Section notes:		

Section C Facilities and Equipment

No	Question/Notes	Answer
1	Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management The plant must demonstrate that the water supply is potable and that potability is maintained at all times. Potability must meet local requirements at a minimum. Water lines and hose drops must be fitted with backflow prevention devices that are tested by a trained inspector at least annually.There can be no dead ends on potable water lines. Hose nozzles must not be submerged in water reservoirs or left laying on the floor. An adequate supply of hot and cold water must be readily available for production, sanitation and handwashing. The facility must have a procedure for handling backed up drains.	Acceptable
2	Plant Construction and Design The construction of the facility must be such that it facilitates the production of wholesome product and that it meets the customer and regulatory food safety and quality requirements. Materials must be easily cleanable, floors well drained and drains must have traps and covers. The plant must be designed in a manner appropriate to prevent the contamination of product. A glass and brittle plastic program must be in place. The plant construction allows excellent line flow, space for cleaning and service around all processing lines. Individual processing areas are separated by walls to assure separation of each production function.	Excellent

Section C Facilities and Equipment

No	Question/Notes	Answer
3	Plant Condition (Walls, Ceilings, Floors, etc.) Walls, ceilings and floors must be well maintained, orderly, clean and sealed. No evidence of water leakage, rust or flaking paint. No string, rope, wire or tape used as supports or temporary repairs. Overhead structures must be clean and free of buildup. Excellent design and condition of the facility. Floors, walls and ceilings are very clean and in like new repair.	Excellent
4	Ready To Eat (RTE) Operational Areas Ready to Eat areas must be separated and effectively isolated from other operations. Filtered air supplies must provide a positive room air pressure and filters must be routinely inspected and maintained for maximum efficiency. All products are processed in RTE designed facilities that are tightly controlled by employee badges related to access location.	Excellent
5	Employee Support Facilities The cafeteria, locker room and toilet facilities must be adequately sized, physically separated from food production areas and maintained in a sanitary condition. Toilet facilities must be well ventilated, doors must be self-closing and can not open directly into the production areas. Signs must be clearly posted in locker rooms, toilet facilities and at entrances to work areas reminding employees to wash and sanitize their hands before starting work and when leaving toilet facilities.	Acceptable
6	Handwashing Facilities Hand washing facilities must be provided in locker rooms, toilet facilities and at entrances to work areas. They must be adequate in size, quickly deliver tempered water and maintained with hand soap and single service towels. Hands-free activated faucets must be available in and adjacent to processing areas.	Acceptable
7	Equipment Layout, Design and Conditions Equipment must be designed, installed and maintained in a manner that provides a safe, wholesome and quality product with easy access for cleaning and sanitizing. Product contact surfaces must be constructed with materials that are smooth, impervious, non-toxic, non-absorbent and corrosion resistant with appropriate covers and no metal-to-metal contact between moving parts. Equipment is state of the art with auto control centers, with PC monitors and observation cameras. Processing operations are maintained from control rooms.	Excellent
8	Plant Lighting and Protection Adequate illumination must be provided and lighting must be protected from breakage and possible contamination. Light fixtures must be maintained clean, free of cracks, dust or other materials that could cause contamination.	Acceptable
9	Maintenance Standard (Support of GMPs, Housekeeping, Lubricants There must be a documented preventative maintenance program that covers the equipment and facilities. Permanent repairs must be made promptly. Food-grade and non-food grade lubricants can not be stored together.	Acceptable

Section notes: It was suggested that original installed elevated walkways in the RPB packaging area above the finished product lines have higher kick plates added. All line cross overs have adequate kick plates.

Section D Sanitation, Housekeeping and Hygiene

No	Question/Notes	Answer
1	Master Sanitation List and Monitoring There must be a documented cleaning procedure for operational areas, equipment, warehouse, storage, maintenance, employee support areas and other plant areas. There must be scheduled tasks for all cleaning procedures that are monitored and documented.	Acceptable
2	Standard Sanitation Operating Procedures and Monitoring There must be documented Standard Sanitation Operation Procedures detailing the cleaning methods and frequency of cleaning for all equipment and facility structures. All cleaning and sanitizing must be documented and monitored Records must be kept of all deficiencies found and the corrective action that is taken to bring the equipment into a sanitary condition and prevent a reoccurrence.	Acceptable

Section D Sanitation, Housekeeping and Hygiene

No	Question/Notes	Answer
3	Cleaning Chemical and Sanitizer Control There must be procedures that specify the proper dilution of chemicals and/or sanitizers. All chemical containers must be properly labeled and used for their intended purpose only. Chemicals must be securely stored during periods of non-use.	Acceptable
4	Pre Op Monitoring and Corrective Action A routine documented inspection program must be in place to assess sanitation practices and conditions prior to daily operation. Deficiencies must be noted and corrective actions taken.	Acceptable
5	Verification of Cleaning Effectiveness The effectiveness of the sanitation program must be monitored visually prior to production and supplemented with an objective measurement at a frequency that demonstrates effectiveness.	Acceptable
6	Operational Housekeeping and Monitoring All areas of the plant must be kept clean, orderly and free from accumulation of litter. Garbage, trash and waste materials must be accumulated in identified containers and disposed of properly. Floor drains must be kept clean, odor free and covered. No tool storage or materials on top of equipment, electrical boxes or window ledges.	Acceptable
7	Personal Hygiene and Good Manufacturing Practices There must be a dress code that is enforced for everyone entering the facility. Employees must wear clean clothing and shoes appropriate for the working conditions. Hair restraints must be worn in all processing and warehouse areas. Employees working in production areas must not wear fake fingernails, fingernail polish, jewelry, rings, or watches, etc. Employees cannot work in food processing areas if they have a communicable illness, or open sores. Employees must wash their hands before starting work and any time necessary to avoid product contamination. If gloves are worn, they must be intact, with no holes, and kept clean. There must be a means to avoid contamination of outer clothing when using the toilet facilities. Eating, drinking or using tobacco products must not be permitted except in designated areas.	Acceptable
8	RTE Sanitation and Corrective Action Employees working in Ready to Eat (RTE) areas must take additional precautions to protect product from microbiological cross contamination. Personnel handling RTE food must wear sanitary gloves.	Acceptable
9	GMP Self Inspections and Corrective Actions Internal GMP self-inspections must be conducted to verify compliance to policies and to evaluate the effectiveness of the policies. Follow-up audit activities must be conducted to record the effectiveness of corrective actions for deficiencies and repeat items.	Acceptable

Section notes: All systems are Clean In Place and cleaning is conducted by each of the line operators. Master and Standard cleaning is completed by personnel responsible for each processing zone. Internal GMP self-inspections are conducted to verify compliance to policies and to evaluate the effectiveness of the policies. All aspects of sanitation and GMP compliance are included in the daily checklist used in each area. Follow-up audit activities are conducted to record the effectiveness of corrective actions for deficiencies and repeat items.

Section E Rodent and Pest Control Management

No	Question/Notes	Answer
1	Documented and Specific Pest Control Program There must be a pest management program in place that is overseen by a licensed Pest Control Operator (PCO). Site maps for all traps and bait stations, documentation of services, Material Safety Data Sheet (MSDS), the PCO applicators license and letter of insurance must be current and on file.	Acceptable
2	Outside Premises Management (Grounds, Waste Disposal Areas) The buildings exterior and grounds must be well maintained and free from pest harborages. Adequate trash and waste disposal facilities must be available and the premises must be free from standing water that could attract pests.	Acceptable
3	Inside Premises Management Interior conditions must be orderly, clean throughout and allow for easy access and evaluation along walls. Control measures must be used at distances from food or food contact surfaces to avoid any potential for contamination. Trapping devices must be in proper working condition and no bait stations can be used inside the plant or warehouse.	Acceptable

Section E Rodent and Pest Control Management

No	Question/Notes	Answer
4	Pest Tight Doors and Entrance Closures All doors must be tight closing and no exterior holes/cracks in walls, pipe chase, vent openings, windows, etc., to provide easy access to pests.	Acceptable
5	Secure Storage and Documentation of Pest Related Chemicals If pest related chemicals are stored on site, they must be stored in a secured location with limited access. An up to date inventory log of chemicals must be maintained. Containers must be destroyed once empty. Safety precautions for storage of pest related chemicals must be available.	Acceptable
6	Activity Reports Detailed with Corrective Actions Activity reports must be available with specific details about all pest activity observed. Recommended corrective actions should be included on the reports as well as details about the chemicals used in response to the observed activity. Activity reports must be signed by the PCO and by a designated plant representative. All deficiencies require documented corrective action.	Acceptable

Section notes: Site maps for all traps and bait stations were current, Material Safety Data Sheet (MSDS) and the PCO applicator's license and letter of insurance were current and on file.

Section F Receiving and Inventory Control

No	Question/Notes	Answer
1	Incoming Vehicle Review and Documentation There must be a written inspection program that describes acceptable and/or unacceptable conditions for all inbound carriers. All inbound carriers must be inspected for food safety, quality and security related concerns at the time of receiving. QA approves the product (each lot) after sampling, comparing to COA's, product specifications and releasing for movement into the warehouse acceptable inventory locations after compliance to all safety, quality and physical specifications are verified.	Excellent
2	Specific Receiving Policies with Inspection and Acceptance Plans All ingredients and supplies must be purchased from approved vendors. Current specifications for purchased ingredients and supplies must be available. Incoming materials and ingredients must be inspected for damage, contamination and other unacceptable conditions as described by the receiving policy. Records must be maintained along with supplier codes for lot traceability.	Acceptable
3	Release Criteria for Ingredients All ingredients must be maintained in a secure fashion and released for use against a defined approval program. An inventory management system must be in place to assure proper rotation.	Acceptable
4	Storage and Handling Policies and Practices There must be established procedures to assure that ingredients and supplies do not become a source of contamination. Receiving areas and storage locations must be maintained in a clean and sanitary manner. All ingredients and supplies must be held under conditions necessary to maintain product integrity.	Acceptable
5	Bulk Receiving Systems Sanitation and Monitoring Bulk ingredient handling and storage equipment must be maintained in a sanitary and secure manner. The cleaning procedures and frequencies must be documented. Bulk ingredients carriers are secured inside the building and all connection lines are maintained in a sanitary manner. Bulk milk products, and oil are received. Documented cleaning procedures and frequencies are established and followed	Excellent
6	Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds All restricted or sensitive ingredients, potentially toxic chemicals and allergenic materials must be maintained under strict control and stored separately to minimize the potential for accidental product contamination.	Acceptable

Section notes:

Section G Process and Product Evaluation

No	Question/Notes	Answer

Section G Process and Product Evaluation

No	Question/Notes	Answer
1	Process Control and Documentation Procedures There must be established process control procedures to assure products meets all food safety requirements. In-process ingredients and products must be adequately protected and properly labeled with date and lot number. Process control systems are very well developed and documented. Most are highly automated. Process control procedures are established, monitored and documented to assure product is manufactured to meet all food safety requirements.	Excellent
2	Specification and Formulation Control and Accuracy Records must be available that demonstrate compliance to product formulations and finished product specifications. Test protocols and frequencies must be followed as identified in the specification. Production records must be maintained for twelve months beyond product shelf life. All formulas are controlled at the division headquarters in Columbus, Ohio. Software is uploaded locally and access is very limited. All current specifications are controlled locally by QA. Records are available that demonstrate compliance to product formulations and finished product specifications.	Excellent
3	Routine Calibration of Operational Equipment and Measuring Devices (such as thermometers, scales, flow meters, counters, metal detectors, etc.) Key process control devices must be calibrated by an outside contractor at least annually. All devices must also be monitored internally at a frequency adequate to verify accuracy during day to day usage. Corrective actions must be documented when measuring devices are found to be out of calibration.	Acceptable
4	Foreign Material Control All finished product must be scanned through an instrument calibrated to identify and separate contaminated product. There must be a written procedure describing the maintenance, set-up and verification tests of detector systems with documentation to show the procedures are being followed. The cause for any rejection must be recorded on a calibration/test log.	Acceptable
5	Application of Statistical Control Statistical control must be used to determine the capability of the process equipment and the setting of critical limits for critical control points.	Acceptable
6	Allergen and Sensitive Ingredient Controls In facilities where allergens or sensitive ingredients are present, there must be detailed procedures to prevent the contamination of other products. Products containing allergens must be labeled as required by regulations.	Acceptable
7	Documentation Showing Product Meets Specifications Records must be maintained to assure that the appropriate product attributes were evaluated and that the results were consistent over time. Finished products are inspected and tested. Product is not shipped until all parameters meet specification and are approved by management.	Excellent
8	Rework and Carryover Products There must be a documented procedure for managing rework and carry over products. Rework must be traceable to its original production and to finished product. Production dates and original lot numbers must be carried forward in production documents. Rework and carry-over must be kept to a minimum and used promptly at the first opportunity. There must be a routine and documented "clean break" in the rework/carryover cycle.	Acceptable
9	Analytical Records Management Established systems must be used to properly store and retrieve analytical information, documents, reports, records, etc.	Acceptable
Section notes:		

Section H Packaging and Labeling

No	Question/Notes	Answer

Section H Packaging and Labeling

No	Question/Notes	Answer
1	Label Accuracy and Regulatory Compliance There must be procedures in place to assure products are labeled properly and that the labels meet regulatory requirements. All labels are maintained in a secure location until the evaluations are completed. Obsolete/irregular labels are well marked on Hold and held in a secure location waiting for proper destruction/disposition. On-line scanners are used to read label bar codes and hourly verification of the scanners is conducted.	Excellent
2	Documented Net Weight or Count Compliance Policy and Performance Plants must have a documented policy for net weight, liquid contents or product count to verify compliance to label requirements and/or specifications. Net weight equipment automatically adjust each pocket on the filler to compensate for any over/under fill conditions.	Excellent
3	Clear Manufacturing Codes on Individual and Cased Product All product must have a code date that is of such size, color and contrast to afford easy legibility at a reasonable distance. Each individual sell unit must have a production or lot code. Packages within the sell unit must have a lot code. The individual package code dates and the case codes dates must be the same.	Acceptable
4	Package Integrity and Function for Distribution All packaging must be designed and assembled to provide protection for the product from environmental and shipping conditions. Verification of proper sealing and closure of the packaging must be conducted.	Acceptable
5	Label Security and Obsolete Label Controls There must be a written plan in place to prevent the use of unauthorized or incorrect labels.	Acceptable
6	Tamper Evident Packaging Tamper evident packaging must be used and a documented monitoring program must be in place.	Acceptable
Section notes:		

Section I Storage and Shipping

No	Question/Notes	Answer
1	Warehouse and Finished Product Management Warehouse conditions must be maintained in a manner to assure product integrity. Finished product and packaging materials must be held separated and away from chemicals. Product not "cleared" for shipment must be clearly identified and stored in a location where it is not likely to be shipped in error.	Acceptable
2	Retained and Returned Products There must be documented procedures requiring identification, secured segregation, documentation, evaluation, disposition and reconciliation of non-conforming retained and returned products that is placed on hold. Returned products must be placed on hold immediately, designated areas must be established for retained and returned products and an inventory log must be maintained showing current product on hold and the disposition of all released product with proper authorization.	Acceptable
3	Storage Facility and Dock Maintenance Warehouse storage areas must be clean and orderly and have adequate space around the periphery for access, inspection and cleaning. Items must be stored off the floor, floors and walls must be in good condition and emergency doors must be tight fitting. Shipping docks, dock plates and levelers must be clean and kept orderly.	Acceptable
4	Transport Condition There must be written procedures for acceptable carrier conditions available to shipping personnel. Outbound trailers must be inspected and results must be documented. No product can be loaded into unacceptable carriers. When non-dedicated carriers are used, trailer logs must be assessed to determine if unacceptable materials had been present.	Acceptable
5	Release Authorization to Ship Product Release authorization must be required before any product is shipped.	Acceptable

Section I Storage and Shipping

No	Question/Notes	Answer
6	Product Traceability Procedures must be established to effectively trace specific lots of ingredients, food contact packaging and finished products through the shipping and distribution channels. Traceability exercises must be conducted at least twice per year to the first level of distribution. Management assessments of each traceability exercise must be conducted. The most recent traceability exercise must demonstrated a 99.5% to 105% level of accountability within 4 hours.	Acceptable

Section notes: Two product traceability studies were conducted: (1) 12/05/07 for 26,743 cases of Similac Sensitive Label, shipped to multiple locations (1st point of distribution). 100% recovery, within a reasonable time period.
(2) 7/16/07 for RPB Bottles for 38,605 cases 100% recovered from multiple locations, within a reasonable time period.
Suggest that all traceability exercises be documented to within 4 hour time limit. (Actually they contacted all points of distribution and received verification that products were received beyond first point of distribution requirement).

Section J Analytical Records and Laboratory Support

No	Question/Notes	Answer
1	Laboratory Facility and Staffing Laboratories must be adequately equipped and staffed to provide the essential technical support. Lab staff qualifications must be documented, toxic supplies must be securely stored and properly labeled and the laboratory must be clean, orderly and well lit. A total of 42 lab employees, 24 in the chemistry lab, 9 in the micro lab, and 9 dedicated to incoming materials, control the evaluation of materials and final product conformance to required standards. Laboratories are adequately equipped and staffed to provide the essential technical support.	Excellent
2	Laboratory Procedures and Documentation Laboratory procedures must be documented, authorized and dated. Testing procedures must be based on recognized and approved procedures and documentation of all testing must be available. Laboratory procedures are documented, authorized and date, by the Division headquarters.. Testing procedures are based on recognized and approved procedures and documentation of all testing is available.	Excellent
3	Laboratory Equipment Calibration Calibration records must be maintained for all laboratory balances and test equipment for calibrations performed by a certifying company as well as all internal calibration check.	Acceptable
4	Analytical Accuracy Verification Documented evidence must be available that demonstrates laboratory test results are accurate and reliable.	Acceptable

Section notes:

Section K Food Defense

No	Question/Notes	Answer
1	Management A risk assessment must be conducted by an established Food Defense team to evaluate all vulnerabilities and risks that exist in the facilities process. A documented Food Defense program must be in place. The facility must have a registration number from the applicable regulatory agency and unusual occurrences must be documented and assessed by management. A documented Food Defense program has been identified, organized, communicated and implemented and is fully understood by plant employees, suppliers and customers.	Excellent
2	Human Element All individuals entering the facility must show proof of identification. A screening program must be in place for all employees. Temporary employees must be fully supervised at all times. Contractors and visitors must be required to show identification and sign in and out. Visitors must be accompanied while in the facility. A current roster of employees and work assignments must be maintained and employees must be prohibited from bringing personal items into processing areas. There must be a program in place to train Food Defense rules at the facility with documentation for each individual.	Acceptable

Section K Food Defense

No	Question/Notes	Answer
3	Facility Procedures must be in place to address access to and from the plant grounds and facility. A schematic of the facility and outside grounds must be available that identifies all entrances into the building, accesses to the roof and sensitive areas. Access to sensitive areas and utilities must be restricted. There must be a documented process for issuing, tracking and retrieving keys, identification badges and passes for the buildings and for secure areas. A schematic of the facility and outside grounds is available that identifies all entrances into the building, accesses to the roof and sensitive areas. Cameras, lighting, fencing, and security service is very complete. Access to sensitive areas and utilities is restricted. When not in use, non-traffic doors, dock doors and utility are kept locked and only accessed by key cards that record multiple pieces of information. access is secured.	Excellent
4	Operations The facility must be evaluated for vulnerability to sabotage with documented procedures developed to address areas of concern. Non-employee drivers and delivery personnel must have a designated waiting areas. Trucks and/or trailers must be inspected before unloading. There must be a procedure for the receipt of damaged product. Vehicles must be kept secured when not in use and after loading is completed. Seal numbers must be recorded.	Acceptable
Section notes:		

Section 1A Ingredients of Concern

No	Question/Notes	Answer
1	Does the plant use or store Peanuts or Peanut Products?	No
2	Does the plant use or store Tree Nuts?	No
3	Does the plant use or store Crustacea?	No
4	Does the plant use or store Fish?	No
5	Does the plant use or store Egg or Egg Products?	No
6	Does the plant use or store Milk or Milk Products?	Yes
7	Does the plant use or store Soybean or Soy Products?	Yes
8	Does the plant use or store Wheat, Corn (Maize) or Related Grains?	No
9	Does the plant use or store Mollusks?	No
10	Does the plant use or store Seeds?	No
11	Does the plant use or store Cottonseed Products?	No
12	Does the plant use or store Legumes?	Yes
13	Does the plant use or store Sulfites?	No
14	Does the plant use or store FD&C Yellow #5 or #6?	No
15	Does the plant use or store Monosodium Glutamate, Autolyzed yeast, Hydrolyzed protein?	No
16	Does the plant use or store Meat?	No
17	Does the plant use or store Poultry?	No
Section notes:		

* Represents Non Compliances.

If you have any questions about this report, please contact your NSF Project Manager, Betty Teasdale, at 734-913-5767 or

bteasdale@nsf.org.